

**NIX- permethrin shampoo**  
**Insight Pharmaceuticals LLC**

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**Nix Creme Shampoo - 63736-024**

**NIX®**

**Drug Facts**

**Active ingredient (in each fluid ounce)**

Permethrin 280 mg (1%)

**Purpose**

Lice treatment

**Use**

treats head lice

**Warnings**

**For external use only**

**Do not use**

- on children under 2 months of age
- near the eyes
- inside the nose, ear, mouth, or vagina
- on lice in eyebrows or eyelashes. See your doctor.

**Ask a doctor before use if you are**

allergic to ragweed. May cause breathing difficulty or an asthmatic episode.

**When using this product**

- keep eyes tightly closed and protect eyes with a washcloth or towel
- if product gets into the eyes, immediately flush with large amounts of water
- scalp itching or redness may occur

**Stop use and see a doctor if**

- breathing difficulty occurs
- eye irritation occurs
- skin or scalp irritation continues or infection occurs

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

## **Directions**

### **Inspect**

- all household members should be checked by another person for lice and/or nits (eggs)
- use a magnifying glass in bright light to help you see the lice and nits (eggs)
- use a tool, such as a comb or two unsharpened pencils to lift and part the hair
- look for tiny nits near the scalp, beginning at the back of the neck and behind the ears
- small sections of hair (1-2 inches wide) should be examined at a time
- unlike dandruff, nits stick to the hair. Dandruff should move when lightly touched.
- if either lice or nits (eggs) are found, treat with Nix® Creme Rinse

### **Treat**

- wash hair with a shampoo without conditioner. Do not use a shampoo that contains a conditioner or a conditioner alone since this may decrease the activity of Nix®. Rinse with water.
- towel dry hair so it is damp but not wet
- shake the bottle of Nix® well
- completely saturate the hair and scalp with Nix®. Begin to apply Nix® behind the ears and at the back of the neck.
- keep Nix® out of the eyes. Protect the eyes with a washcloth or towel.
- leave Nix® on the hair for 10 minutes, but no longer
- rinse with warm water
- towel dry hair and comb out tangles
- if live lice are seen seven days or more after the first treatment, a second treatment should be given

### **Remove Lice/Nits**

- remove nits by combing the hair with the special small tooth comb provided. Remaining nits may be removed by hand (using a throw-away glove), or cutting the nits out.
- use the nit comb provided and make sure the hair remains slightly damp while removing nits
- if the hair dries during combing, dampen it slightly with water
- part the hair into 4 sections. Work on one section at a time. Longer hair may take more time (1-2 hours).
- start at the top of the head on the section you have picked
- with one hand, lift a 1-2 inch wide strand of hair. Get the teeth of the comb as close to the scalp as possible and comb with a firm, even motion away from the scalp to the end of the hair.
- use clips to pin back each strand of hair after you have combed out the nits
- clean the comb completely as you go. Wipe the nits from the comb with a tissue and throw away the tissue in a sealed plastic bag to prevent the lice from coming back.
- after combing, recheck the entire head for nits and repeat combing if necessary
- check the affected head daily to remove any nits that you might have missed

### **Other information**

- read all the directions in the Consumer Information Insert and warnings before use. Keep the carton. It contains important information.
- store at 20° to 25°C (68° to 77°F)

### **Inactive ingredients**

balsam canada, cetyl alcohol, citric acid, FD&C yellow no. 6, fragrance, hydrolyzed animal protein, hydroxyethylcellulose, polyoxyethylene 10 cetyl ether, propylene glycol, stearylalkonium chloride, water, isopropyl alcohol, methylparaben, and propylparaben

## Questions or comments?

### PRINCIPAL DISPLAY PANEL

63736-024-02

Nix®

Creme Rinse

Permethrin /Lice Treatment

NET WT 2 FL OZ (59 mL)



### PRINCIPAL DISPLAY PANEL

63736-024-04

Nix®

Creme Rinse

Permethrin /Lice Treatment - Family Pack

NET WT 4 FL OZ (2 - 2 FL OZ (59 mL))



## NIX

permethrin shampoo

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-024
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PERMETHRIN (UNII: 509F88P9SZ) (PERMETHRIN - UNII:509F88P9SZ)	PERMETHRIN	1 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
CANADA BALSAM (UNII: K304V198B3)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
CETETH-10 (UNII: LF9X1PN3XJ)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
STEARALKONIUM CHLORIDE (UNII: 0OUO26BB88)				
WATER (UNII: 059QF0KO0R)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
METHYL PARABEN (UNII: A2I8C7HI9T)				
PROPYL PARABEN (UNII: Z8IX2SC1OH)				
Product Characteristics				
Color	ORANGE (Light Orange)		Score	
Shape			Size	
Flavor			Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-024-02	1 in 1 CARTON	11/15/2013	
1		59 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:63736-024-04	2 in 1 CARTON	11/15/2013	
2		59 mL in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
NDA	NDA019918		11/15/2013	06/30/2023

**Labeler** - Insight Pharmaceuticals LLC (055665422)